December 31, 2008

Microelectrodes and Instrumentation for Neuroscience
Research and Clinical microTargeting

FHC Corporate & Manufacturing
1201 Main Street
Bowdoin, ME
04287-7302 USA

Tel: 207-666-8190
US & Can.: 800-326-2905
Fax: 207-666-8292
E-mail: fhcinc@fh-co.com
www.fh-co.com

FHC Europe
(TERMOBIT PROD srl)
129 Barbu Vacarescu Str,
Sector 2
Bucharest 020272
Romania

MEDICAL DEVICE CORRECTION

FHC, Inc. and Medtronic
microTargeting™ Drive System and Drive System Accessories (Motor/Encoder)

ACTION REQUIRED

Please ensure this notice is forwarded **immediately** to all users of the above models

Dear Healthcare Provider:

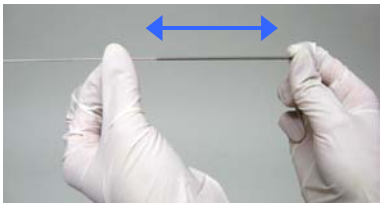
FHC is writing to inform you of a potential concern affecting a component of your FHC microTargeting™ Drive System, the Array Insertion Tubes.

FHC has received six reports over the last four years regarding insertion tube performance issues. Although no patients have been injured by such a product failure, and no single root cause has been identified, we believe the potential risks are serious enough to give this concern emphasis.

FHC has amended the warnings related to the pre-use inspection of the insertion tubes. Insertion tubes are extremely delicate and can be damaged during shipping and handling. Just as one inspects the microelectrode tips and contacts before use, so too should one ensure that the tubes are straight and fully intact. FHC will be adding the following recommendations to our microTargeting™ Drive Directions for Use (or User Manual):

⚠ Warning: As the most critical component of a procedure, delicate insertion tubes should always be carefully inspected before use because damage to them can cause targeting errors and impact patient safety. Handle insertion tubes and spacer tubes carefully to prevent bending.

- Check to be certain that all insertion tube components are secure; with the stylet removed, grasp the large diameter collar at the proximal end and the smaller distal end and administer a gentle pull, being careful not to bend or twist the tube. If there is any movement, the insertion tube should not be used.



- Check to be certain that tubes are straight; with the collar over the edge roll the insertion tube over a flat surface or in the DBS measurement tool slot.

In addition to the above noted amendments to the Drive Directions for Use, revisions are underway to the Drive and Accessories documents which are a result of our continuous risk assessment and product improvement efforts. This notification includes a summary of all new WARNINGS and CAUTIONS, as well as those that have been significantly modified. The Directions for Use improvements will also include illustrations and photographs for greater clarity as well as a CD of certified translations. FHC anticipates having the new Directions for Use ready for release in January 2009.

FHC IS REQUIRING CUSTOMERS TAKE THE FOLLOWING ACTIONS:

1. Please include this Notification in your current User Manual for easy reference.

2. To acknowledge receipt of this communication and to ensure prompt delivery of the revised Directions for Use, please contact us via:
   Website log in: www.fh-co.com/mT08RSP
   Email address: quality@fh-co.com

   Or complete the box below and transmit via facsimile to:
   Fax: +1-207-666-8309

If you have any questions concerning this notification you may contact Keri Seitz, Senior Regulatory Affairs Associate at +1-207-666-8190, x2210; or 1-800-326-2905 (US and Canada).

We appreciate your attention to this notification. Our goal is to provide our system users with the most current and helpful information possible. We thank you in advance for ensuring that this document is reviewed by all system users and for your timely response.

Sincerely,

Fred Haer
President

Please send the revised Direction for Use to:

Name: _____

Department: _____

Institution:_____

Street Address: _____

City, State: _____

Country, Postal Code _____

Email/Phone: _____

IMPORTANT: Please complete this page and fax to +1-207-666-8309. This acknowledges your receipt of this notice and ensures prompt delivery of the new microTargeting™ Drive System Directions for Use.

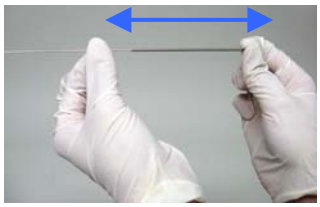
microTargeting™

microTargeting™ Drive System - Directions for Use
New Warning & Caution Statements

New Warnings:

⚠ As the most critical component of a procedure, delicate insertion tubes should always be carefully inspected before use because damage to them can cause targeting errors and impact patient safety. Handle insertion tubes and spacer tubes carefully to prevent bending.

- Check to be certain that all the insertion tube components are secure; with the stylet removed, grasp the large diameter collar at the proximal end and the smaller distal end and administer a gentle pull, being careful not to bend or twist the tube. If there is any movement, the insertion tube should not be used.



- Check to be certain that tubes are straight; with the collar over the edge roll the insertion tube over a flat surface or in the DBS measurement tool slot.

⚠ Always confirm the tightness of thumbknobs and set screws, especially those holding the frame adapter, before beginning the procedure. The stereotactic adapter must be securely held in the frame mount so that the drive system cannot move or rotate.

⚠ Improper cable connections may cause erroneous results including unintended stimulation through metal contacts in the brain.

⚠ If any error or erratic function is observed, discontinue use of the drive immediately and evaluate the potential impact to patient safety before continuing its unmitigated use.

⚠ While often snug, all tubes used with the microTargeting™ Drive System have been designed to be inserted and removed by hand. A tool should be used only as a last resort for tubes that cannot be removed by hand; use of tools in this manner indicates system repair is necessary.

⚠ Prior to use the microTargeting™ Drive System should be completely assembled and correct operation verified to ensure that all components function properly. Improper set-up of equipment may lead to serious patient injury.

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New Cautions:

CAUTION: The drive system and its associated insertion tubes are not MRI compatible.

CAUTION: When tightening set screws, use only the tool provided. When tightening thumbknobs, hand tighten only. Over-tightening can cause damage to the drive system and adversely affect targeting.

CAUTION: Do not over tighten these screws as it may damage the microelectrode or DBS electrode. (See figures a and b.)

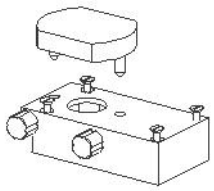
a.

CAUTION: FHC's regulatory clearance requires that microTargeting™ Drive systems and components be serviced and recalibrated every 100 uses or factory evaluated on an annual basis.

CAUTION: To ensure proper drainage, remove cover during cleaning and sterilization. (See figure c.)

b.

c.



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L012-08-XXXX December 31, 2008

microTargeting™ Drive Accessories (Motor/Encoder)- Directions for Use
New Warning & Caution Statements

New Warnings:

⚠ None of the Drive Accessories should be sterilized; use the sterile draping system as described.

⚠ In the event of any Drive Accessory failure, erratic function or motor stall, remove it and proceed using the microTargeting™ Drive manually.

⚠ Always confirm that the microTargeting™ Drive is set at 0mm when zeroing the microTargeting™ Controller. (As a safety feature, the Display Unit cannot be re-zeroed without powering off the Module.) Not doing so will cause the drive limit to be incorrect and also will cause the Controller Display to be out of sync with the drive position as read on the drive scale.

⚠ During the procedure, periodically compare the physical scale depth reading with Controller reading to ensure proper operation. If the two scales differ by more than 100 microns, discontinue use of the Display Unit and proceed manually.

⚠ The microTargeting™ Controller has been factory set to enforce a software drive limit of 50mm which corresponds with the maximum travel of the microTargeting™ Drive. This limit may be changed through the serial interface of the microTargeting™ Controller. However, setting the limit above 50mm could result in drive travel beyond the expected target.

⚠ Do not operate the controller unit in the presence of flammable anesthetics.

New Cautions:

CAUTION: Unauthorized field repairs may affect calibration and function. Units requiring repair should be returned to FHC or an authorized representative for service.

CAUTION: FHC's regulatory clearance requires that microTargeting™ Drive systems and components be serviced and recalibrated every 100 uses or factory evaluated on an annual basis.

CAUTION: Pre-use check should include retracting or advancing the Drive motor using the handheld remote. Confirm that the knob can be turned to its clockwise (advance) and counterclockwise (retract) limits and when released returns to the center position. No movement of the Drive should occur when the remote control knob is in the center resting position. If there are any abnormalities, perform the calibration procedure.

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CAUTION: The cover is provided to protect the opening in the top of the microTargeting™ Drive when an accessory is not attached. Failure to use the cover could allow debris to enter the drive mechanism. The cover should be removed during cleaning and sterilization to allow proper drainage from this mechanism.

CAUTION: Never turn the manual advancement knob on the microTargeting™ Drive while a motor is engaged. This can damage both the motor and the drive.

CAUTION: The accessory components should be inspected visually prior to each use for physical damage, frayed or kinked cables or damaged connectors.

CAUTION: Do not zero the Display Unit until prompted. Failure to do so will result in display errors.

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microTargeting Drive System – microTargeting Array Insertion Tube w/Stylet

Model numbers;

66-DA-EN,
66-DA-EN-02,
66-DA-ME,
66-DA-ME-MOD,
66-EL-MC,
66-EL-MS,
66-EL-MS-01,
66-EL-MS-02,
66-EL-MS-03,
66-EL-MS-04,
66-EL-PD,
66-ZD-MD,
66-ZD-MD-01,
MODMT-DS-AM,
MT-DS,
MT-DS-01,
MT-DS-AM,
MT-DS-MD,
MT-PA,
MT-SYSTEM,
66-DS-PA,
FC1006,
FC1007,
FC1008,
FC1011,
FC1012,
FC1018,
FC1019,
9033G0601,
9033G0801,
9033G0701,
9033G0702,
9033G0711,
9033G0712,
9033G0713